DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#17

Re: AMBIEN®
Docket No. 93E-0087

APR 19 1993

The Honorable Douglas B. Comer
Acting Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Comer:

This is in regard to the application for patent term extension for U.S. Patent No. 4,382,938, filed by Synthelabo, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for AMBIEN®, the human drug product claimed by the patent.

The total length of the review period for AMBIEN® is 2713 days. Of this time, 1296 days occurred during the testing phase and 1417 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: July 15, 1985.

   The applicant claims November 15, 1984, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND was placed on clinical hold on December 10, 1984, and was removed from hold on July 15, 1985. Therefore, the IND effective date is July 15, 1985.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: January 30, 1989.

   The applicant claims January 26, 1989, as the date the new drug application (NDA) for AMBIEN® was initially submitted. However, FDA records indicate that NDA 19-908 was initially submitted on January 30, 1989.

3. The date the application was approved: December 16, 1992.

   FDA has verified the applicant's claim that NDA 19-908 was approved on December 16, 1992.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Douglas P. Mueller
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